

Dear Sir

Thank you for the opportunity to comment on the Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia.

The following commentary reflects recent experiences operating in a small business environment as an importer of medical devices into Australia.

Unique Device Identification (UDI).

There is clearly significant opportunity in the utilisation of UDI to contribute to patient safety and supply chain efficiencies. To date Australia medical device sponsors have been exposed to the National Product Catalogue (NPC) operated by GS-1 Australia.

The NPC promises significant savings in supply chain efficiencies for sponsors and consumers of medical devices. This promise has led to NPC compliance being listed as an essential trait for all companies wishing to be considered compliant in state tenders throughout Australia. The upside is significant for state health agencies given their successful tenders will be able to provide uniform data for uploading into their ERP systems. The downside is that the success of the NPC has handed a monopoly position to GS-1 Australia as the NPC only accepts GTIN numbers as the unique identifiers

The small business experience with the NPC is far from efficient. Maintaining NPC compliance requires significant resources with absolutely no upside for a small business. Small business can not afford dedicated personal for maintain compliance. Small business sees no return for the annual fees for membership of GS-1 and the NPC. Most small businesses have not achieved the scale to be incorporating expensive digital based tracking/scanning systems in their logistics processes. These small importers are likely never to reach a size where consumers are interested in engaging in electronic data transmissions for invoicing etc. Therefore there is limited upside for these organisations.

The NPC has no scope for unique identifiers that are not GS-1 which further disadvantages sponsors of European and US manufacturers who have elected to use another entity for supplying these numbers.

One of governments greatest responsibilities is to recognise monopoly positions and protect consumers against unfair abuse. Therefore I believe it is essential for government and the TGA to utilise this opportunity to protect sponsors against GS-1 Australia and build a database that is useable for end users regardless of the entity used for provision of an UDI.

In respect to cost recover for this process, I believe there should be a volume based suspension of fees to allow small business to operate through the early growth phases. Small businesses are often the ones left to fill the niche product needs and while these products are highly desirable for specific patients they are often low volume markets with reimbursement frozen at levels not compatible with significant ongoing annual fees.

Sincerely

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